DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

National Mammography Quality Assurance Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: National Mammography Quality Assurance Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on August 22, 2001, from 9 a.m. to 6 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact: Charles Finder, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-3332, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12397. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will review facility inspection findings and current compliance followup actions, the Mammography Quality Standards Act (the MQSA) compliance guidance, facility satisfaction survey, mammography access issues and the future direction of the MQSA program. The committee will also receive updates on the status of accreditation and certification of full field digital mammography, States as certification agencies under the MQSA, and the inspection demonstration project. The MQSA compliance guidance documents, which are in a question and answer format, are available to the public on the Internet at http://www.fda.gov/cdrh/oc01168

mammography. This guidance is being updated continually in response to questions that FDA receives from the public. Additional information regarding guidance updates may be obtained by calling the Information Line.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 27, 2001. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10:30 a.m. on August 22, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 27, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated:

July 6, 2001

Linda A. Suydam,

Senior Associate Commissioner.

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

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